TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
PXK2275P		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/001338	31.01.2005	09.02.2004

International Patent Classification (IPC) or national classification and IPC

A61K47/04(2006.01) , A61K31/282(2006.01) . A61K31/407(2006.01) , A61K31/475(2006.01), A61K31/505(2006.01), A61K31/513(2006.01)

Applicant

KABUSHIKI KAISHA SANGI

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2005/001338

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2005/001338

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	10	YES
	Claims	1-9	NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Aoki, H. et al., "In vitro interaction of carcinostatic substances absorbed on hydroxyapatite microcystals with cells derived from cancers", Transactions of the Materials Society of Japan, 1994, Vol. 15A, pages 3 to 9

Document 2: WO 2002/41844 A2 (Etex Corporation), 30 May 2002

Document 3: JP 6-329557 A (Meiji Milk Products Co., Ltd.), 29 November 1994

Document 4: JP 2-200628 A (Central Glass Co., Ltd.), 8 August 1990

Document 5: JP 4-112832 A (Sangi KK), 14 April 1992

Document 6: JP 1-51266 B2 (Kabushiki Kaisha Arusu Japan), 2 November 1989

Novelty and Inventive Step

Claims 1 to 9

Document 1 sets forth an anti-tumor agent containing doxorubicin and hydroxyapatite with a particle diameter not exceeding 0.1μm (see page 3, Abstract).

Document 2 sets forth an anti-tumor agent containing an anti-tumor ingredient such as fluorouracil and

nanocrystalline hydroxyapatite.

Therefore the invention set forth in claims 1 to 9 of this application is disclosed in document 1.

Claims 1 to 3 and 5 to 9

Document 3 sets forth an anti-tumor agent containing an anti-tumor ingredient and hydroxyapatite with a particle diameter not exceeding 500nm (claims 1 to 6 and embodiment 10).

Therefore the invention set forth in claims 1 to 3 and 5 to 9 of this application is disclosed in document 3.

Claims 1 to 4

Document 4 sets forth an anti-tumor agent containing cisplatin and hydroxyapatite (claim 1).

Therefore the invention set forth in claims 1 to 4 of this application is disclosed in document 3.

Claims 1 to 3

Document 5 sets forth an anti-tumor agent comprising hydroxyapatite-supported platinum (claim 1).

Document 6 sets forth an anti-tumor agent containing a blend of hydroxyapatite and an anti-tumor agent such as adriamycin (embodiment 1; fig. 2).

Therefore the invention set forth in claims 1 to 3 of this application is disclosed in documents 5 and 6.

Inventive Step

Claims 1 to 10

It would not require any particular creative skill on the part of a person skilled in the art to substitute

the anti-tumor ingredient with an appropriate alternative in the anti-tumor agents set forth in documents 1 to 6, and to optimize the particle size of hydroxyapatite. Moreover, a person skilled in the art would be capable of selecting crushing as a method of adjusting particle diameter as necessary.

In addition, in the light of the description of this application, the invention set forth in claims 1 to 10 of this application does not offer a particularly outstanding effect in comparison to the inventions set forth in documents 1 to 6.